BST-486US

Appln. No.: 10/081,641

Amendment Dated March 26, 2009

Reply to Office Action of January 29, 2009

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

(Currently Amended) An introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

a shaft having a distal tip:

an inner sheath mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in the compressed configuration;

an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder; and

anchoring means in at least one of the retrograde portion or the anterograde portion for <u>engaging and</u> anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen and for minimizing relative axial movement between the <u>engaged</u>, <u>anchored</u>, <u>expanded</u> proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.

2. (Canceled)

- 3. (Previously Presented) The introducer of claim 1, wherein the anchoring means comprises an inflatable balloon at or near a proximal end of the device.
- 4. (Original) The introducer of claim 3, wherein the inner sheath defines a lumen connected to an inner region of the inflatable balloon for communication of a fluid to the balloon for inflation of the balloon.
- (Original) The introducer of claim 3, wherein the inflatable balloon is mounted concentrically underneath a retrograde portion of the endoluminal device.

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6. (Original) The introducer of claim 5 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over the balloon and a retrograde portion of the endoluminal device.

- (Original) The introducer of claim 6 further comprising a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer.
- 8. (Original) The introducer of claim 7, wherein the medial sheath has a distal end that terminates proximal of the balloon.
- 9. (Withdrawn) The introducer of claim 5, wherein the anterograde sheath extends proximally over the balloon and a retrograde portion of the endoluminal device.
- 10. (Original) The introducer of claim 1 further comprising a radial spacer for providing sufficient space between the inner sheath and the anterograde sheath to contain the endoluminal device.
- ${\bf 11.\ (Original)\ The\ introducer\ of\ claim\ 10,\ wherein\ the\ radial\ spacer\ is\ attached}$ proximally to the distal tip.
- 12. (Withdrawn) The introducer of claim 2, wherein the anchoring means comprises a holder in the anterograde portion.
- 13. (Withdrawn) The introducer of claim 12, wherein the holder is concentrically mounted to the inner sheath and adapted to prevent distal movement of the endoluminal device during distal advancement of the anterograde shaft.
- 14. (Withdrawn) The introducer of claim 13, wherein the endoluminal device has a length and the holder has a length that is less than the endoluminal device length.
- 15. (Withdrawn) The introducer of claim 12, wherein the anterograde sheath extends over an entire length of the endoluminal device.
- 16. (Withdrawn) The introducer of claim 1, wherein the anterograde sheath extends over an entire length of the endoluminal device.

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17. (Previously Presented) The introducer of claim 1 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a retrograde portion of the endoluminal device; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of a proximal end of the endoluminal device.

- 18. (Withdrawn) The introducer of claim 17, wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in the medial sheath for confining the extended portion between the retrograde sheath and the medial sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.
- 19. (Withdrawn) The introducer of claim 2 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the inner sheath and the retrograde sheath for confining the extended portion between the retrograde sheath and the inner sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the inner sheath.
 - 20. (Withdrawn) The introducer of claim 2 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of a proximal end of the endoluminal device;

wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the medial sheath and the retrograde sheath for confining the extended portion between the retrograde sheath and the medial sheath with the retrograde

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sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.

- 21. (Withdrawn) The introducer of claim 2, wherein the anchoring means comprises a tether attached to a proximal end of the endoluminal device.
- 22. (Withdrawn) The introducer of claim 21 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the tether is attached to a portion of the inner sheath.
- 23. (Withdrawn) The introducer of claim 22, wherein the tether extends proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced.
- 24. (Withdrawn) The Introducer of claim 22, wherein a proximal end of the tether is attached to means for applying an electrical current or a torsional or tensional force.
 - 25. (Withdrawn) The introducer of claim 21 further comprising:
- a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a proximal end of the endoluminal device; and
- a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of the endoluminal device proximal end.
- 26. (Withdrawn) The introducer of claim 25, wherein the tether is attached to one of the medial sheath, the retrograde sheath, or the inner sheath.
- 27. (Withdrawn) The introducer of claim 26, wherein the tether extends proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced.
- 28. (Withdrawn) The introducer of claim 27, wherein the medial sheath comprises a lateral channel through which the tether extends.

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29. (Withdrawn) The introducer of claim 21, wherein the anterograde sheath extends over an entire length of the endoluminal device.

- 30. (Original) The introducer of claim 1 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a proximal end of the endoluminal device.
- 31. (Original) The introducer of claim 30, wherein the anterograde portion extends over a greater length of the endoluminal device than the retrograde portion.
- 32. (Previously Presented) The introducer of claim 30, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another.
- 33. (Original) The Introducer of claim 30, wherein the retrograde sheath and the anterograde sheath laterally overlap one another.
 - 34.-46. (Canceled)
- 47. (Currently Amended) An introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

a retrograde portion;

an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder;

a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion;

an inner sheath mounted concentrically over the shaft;

an endoluminal device mounted concentrically over the inner sheath in the central lumen and having a distal portion contained by the anterograde portion and a proximal

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end contained by the retrograde portion, the distal portion constrained in the compressed configuration by the anterograde sheath and adapted to expand into an expanded state as the anterograde sheath is advanced distally: and

an inflatable balloon mounted radially inside only the retrograde portion and sized to engage.and anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the engaged, <a href="mailto:anchored, expanded proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion.

48. (Withdrawn) The introducer of claim 47 further comprising an inner sheath mounted concentrically over the shaft underneath the endoluminal device, the inner sheath defining a lumen connected to an inner region of the inflatable balloon for communication of a fluid to the balloon for inflation of the balloon, wherein the retrograde portion comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and the inner sheath and extending distally over the balloon and a retrograde portion of the endoluminal device.

49. (Canceled)

- 50. (Withdrawn) The introducer of claim 5, wherein the anchoring means further comprises a holder in the anterograde portion concentrically mounted to the inner sheath and adapted to prevent distal movement of the endoluminal device during distal advancement of the anterograde shaft.
- 51. (Previously Presented) The introducer of claim 30, wherein the retrograde sheath and the anterograde sheath abut one another.